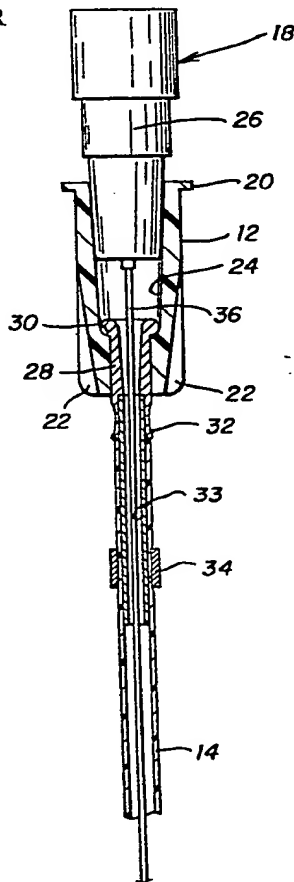




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification<sup>3</sup>:</b>  <b>A61M 25/00</b>	<b>A1</b>	<b>(11) International Publication Number:</b> WO 81/01519  <b>(43) International Publication Date:</b> 11 June 1981 (11.06.81)
<b>(21) International Application Number:</b> PCT/US80/01540  <b>(22) International Filing Date:</b> 14 November 1980 (14.11.80)  <b>(31) Priority Application Number:</b> 099,608  <b>(32) Priority Date:</b> 3 December 1979 (03.12.79)  <b>(33) Priority Country:</b> US  <b>(71) Applicant:</b> BAXTER TRAVENOL LABORATORIES, INC. [US/US]; One Baxter Parkway, Deerfield, IL 60015 (US).  <b>(72) Inventor:</b> KLING, John, E.; 5545 Alpha Road, Apt. 1057, Dallas, TX 75204 (US).  <b>(74) Agents:</b> PRICE, Bradford, R. L. et al.; Baxter Travenol Laboratories, Inc., One Baxter Parkway, Deerfield, IL 60015 (US).		<b>(81) Designated States:</b> AT (European patent), CH (European patent), DE (Auxiliary utility model), DE (European patent), FR (European patent), GB (European patent), LU (European patent), NL (European patent), SE (European patent).  <b>Published</b> <i>With international search report</i>
<b>(54) Title:</b> NEONATE UMBILICAL CATHETER  <b>(57) Abstract</b>  <p>A catheter for use with newborn infants comprises a hub (12) having a chamber (24) therein, a translucent first section of tubing (14), and a radiopaque second section of tubing (16). The first section of tubing (14) is connected to the hub (12) by means of a coupling including an insert (28). The proximal end of the second section of tubing (16) extends in sealing engagement over the distal end of the first section of tubing (14) to form a tight flexible connection. The catheter (10) preferably includes a removable stylet (18) to facilitate insertion.</p>		



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NEONATE UMBILICAL CATHETER

TECHNICAL FIELD

The present invention relates generally to a catheter, and more particularly, relates to an umbilical catheter for use in newborn infants.



## BACKGROUND ART

Newborn infants can develop illnesses requiring treatment by means of umbilical catheters. For example, such catheters have been used widely to perform  
5 transfusions, blood samplings and blood pressure measurements. However, vessel blockage or vessel wall perforation, hemorrhaging, vascular spasms, infection, thrombosis and other complications have occurred in connection with the use of umbilical catheters to treat  
10 sick newborn infants.

The blood vessels of an infant are smaller in terms of length, internal diameter and wall thickness, and are thus more delicate and susceptible to perforation and inflammation during catheterization. Although various  
15 types of catheters have been developed which are suitable for use in youth and/or adults, such catheters have been found too rigid and inflexible for infants.

Umbilical catheters have been developed heretofore, but have suffered from various disadvantages. Catheters  
20 utilizing cannulae formed entirely of polyvinylchloride (PVC) material are too rigid. In addition, a higher incidence of thrombosis has been associated with the use of PVC catheters. The use of radiopaque materials for locating a catheter with a radiograph, and the  
25 use of translucent materials for visual inspection of air or blood passing through the catheter, are well known in the art.

More recently, umbilical catheters have been developed utilizing two sections of tubing, the distal  
30 portion being relatively more flexible than the proximal portion of tubing. Catheters formed of silicone elastomer were found to have several advantages over PVC catheters in the article entitled "Reduced Thrombus Formation with Silicone Elastomer (Silastic) Umbilical Artery  
35 Catheters" which appeared in Volume 56, No. 6 of



Pediatrics in December, 1975. Although more flexible, the silicone elastomer catheters of the prior art have been somewhat difficult to insert, as well as unnecessarily complex in construction and thus relatively expensive to manufacture. A need has thus arisen for a new umbilical catheter of improved construction.



## DISCLOSURE OF INVENTION

The present invention comprises an improved neonate umbilical catheter which overcomes the foregoing and other difficulties encountered in the prior art. In accordance with the invention, there is provided an umbilical catheter comprised of a fitting and two sections of tubing connected together serially. The two sections of tubing are formed of elastomeric material. A removable stylet is preferably used with the catheter to facilitate insertion into a blood vessel. The catheter herein is less expensive to manufacture than those of the prior art and reduces the incidence of complications in catheterization of newborn infants.

More particularly, the present invention comprises a neonate umbilical catheter comprised of a hub or fitting, a proximal section of tubing, and a distal section of tubing connected together in serial relationship. In the preferred embodiment, the proximal tubing section is connected to the hub by means of a rigid insert, inner sleeve and ring. The proximal tubing section is usually relatively less flexible than the distal section. The two sections of tubing are interconnected by stretching the proximal end of the distal section over the distal end of the proximal section. In accordance with the preferred construction, the invention includes a removable stylet extending through the catheter for stiffening the device during insertion into a blood vessel.



## BRIEF DESCRIPTION OF DRAWING

A more complete understanding of the invention can be had by referring to the following Detailed Description in conjunction with the accompanying Drawing, wherein:

5       FIGURE 1 is a top view of an umbilical catheter incorporating the invention;

FIGURE 2 is an enlarged view of the proximal portion of the invention; and

10       FIGURE 3 is an enlarged view of the medial portion of the invention.



## DETAILED DESCRIPTION

Referring now to the Drawing, wherein like reference numerals designate like or corresponding parts throughout the views, and particularly referring to FIGURE 1, there is shown a catheter 10 incorporating the invention. Catheter 10 is especially adapted for transfusions, blood pressure measurement and blood sampling in newborn infants. Under normal conditions, catheter 10 would be enclosed within a sterile package for shipment and storage prior to use.

Catheter 10 includes a fitting or hub 12, a proximal section of tubing 14, and a distal section of tubing 16 connected together in serial relationship. In accordance with the preferred embodiment, a removable stylet 18 is provided with catheter 10 to facilitate insertion thereof into a patient.

Tubing 14 comprises a suitable length of hollow material of transparent or translucent construction to enable visual observation of fluids passing through catheter 10. Blood coloration for instance can thus be readily monitored through tubing 14 without removal of blood samples. Tubing 14 can be constructed of any suitable material, such as vinyl, TEFLON brand material or other polymers. In the preferred embodiment, tubing 14 is of PVC material and is approximately 150 millimeters in length, 2.0 millimeters outside diameter, and 1.2 millimeters inside diameter.

The distal section of tubing 16 is relatively more flexible than tubing 14 and is preferably radiopaque to facilitate x-ray determination of the location of catheter 10. Tubing 16 can be formed of any suitable relatively soft, pliable material such as silicone elastomer. In accordance with the preferred construction, tubing 16





is constructed from silicone elastomer having a length of approximately 200 millimeters, an outside diameter of about 1.7 millimeters, and an inside diameter of about 1.0 millimeters.

5        FIGURES 2 and 3 illustrate the constructional details of catheter 10. FIGURE 2 in particular illustrates the connection between hub 12 and tubing 14. Hub 12 includes a circular flange 20 at the proximal end and several longitudinal ribs 22 about the distal end thereof. Hub  
10    12 can be formed of plastic or other suitable material. A low volume chamber 24 extends through hub 12. Chamber 24 includes a tapered circular socket portion at the proximal end of hub 12, in which the handle 26 of stylet 18 is removably seated.

15        An insert 28, which is preferably formed of metal, extends outwardly from chamber 24 through the narrow end thereof at the distal end of hub 12. Insert 28 and hub 12 are secured together by means of hub shoulder 30 positioned at the junction between the two portions of  
20    chamber 24. Insert 28, which is of hollow construction is thus in fluid communication with the interior of hub 12.

      Tubing 14 extends from a skirt 32 formed at the outside end of insert 28 and over an inner sleeve 33.  
25    The proximal end of sleeve 33 extends underneath skirt 33 and is secured to insert 28 when the skirt is crimped inward. Tubing 14 is securely clamped to sleeve 33 by ring 34. It will thus be apparent that a rigid coupling including insert 28 and inner sleeve 33 provides  
30    reinforcement at the connection between hub 12 and tubing 14.

      A wire 36 extends from handle 26 of stylet 18 through hub 12, insert 28, tubing 14, and a portion of tubing 16. Stylet 18 is thus comprised of a handle 26 and a



length of flexible wire 32, which can be a section of straight wire or helical wound wire. Due to the greater flexibility required of umbilical catheters, it has been desirable to utilize stylet 18 to facilitate insertion of catheter 10, after which the stylet is withdrawn.

FIGURE 3 illustrates the connection between tubing 14 and tubing 16. The proximal end 16a of tubing 16 is stretched over the distal end 14a of tubing 14. In the preferred embodiment, wherein tubing 16 is formed of silicone rubber, this can easily be done by softening the tubing with a solvent and pulling it over tubing 14. This particular form of connection between the two sections of tubing in catheter 10 provides a tight but flexible connection which facilitates manufacture of the catheter and comprises an important aspect of the invention. A flexible outer sleeve 38 of silicone elastomer material, for example, can be provided about the connection between tubing 14 and tubing 16, if desired.

From the foregoing, it will be understood that the present invention comprises a neonate umbilical catheter having several advantages over the prior art. One significant advantage involves the manner of interconnecting the two sections of tubing to retain sufficient flexibility. Another advantage is the use of a rigid insert and inner sleeve to reinforce the connection between the hub and the proximal section of tubing. Other advantages will suggest themselves to those skilled in the art.

Although a particular embodiment of the invention has been illustrated in the accompanying Drawing and described in the foregoing Detailed Description, it will be understood that the invention is not limited to the embodiment disclosed, but is intended to embrace any alternatives, modifications, and rearrangements and/or substitutions of elements as fall within the spirit and scope of the invention.



## CLAIMS

1. A catheter, comprising:
  - a hub including a longitudinal chamber extending therethrough;
  - a proximal section of flexible substantially clear tubing;
  - 5 means for securing one end of said proximal section of tubing to said hub, said proximal section of tubing being in fluid communication with the chamber inside said hub; and
  - 10 a distal section of flexible radiopaque tubing, one end of said distal section of tubing extending in sealing engagement over the other end of said proximal section of tubing such that said sections of tubing are connected in fluid communication.



2. The catheter of Claim 1, wherein said proximal section of tubing comprises a length of tubing of predetermined size constructed of material selected from the group consisting of plastic and elastomeric materials.

3. The catheter of Claim 1, wherein said distal section of tubing comprises a length of tubing of predetermined size constructed from silicon elastomer.

4. The catheter of Claim 1, wherein the chamber in said hub is longitudinally tapered and substantially circular in cross section.

5. The catheter of Claim 1, wherein the means for connecting said proximal section of tubing to said hub comprises:

a hollow rigid insert having a proximal end positioned inside the chamber in said hub and secured thereto, and a distal end extending outwardly from said hub; and

means for clamping said proximal section of tubing to the distal end of said insert.

6. The catheter of Claim 1, including:  
flexible sleeve means surrounding the connection between said proximal and distal sections of tubing.

7. The catheter of Claim 1 including:  
removable stylet means extending through said hub, proximal section of tubing, and a portion of said distal section of tubing for reinforcing said catheter during insertion.



8. An umbilical catheter, comprising:

a hub including a longitudinal chamber extending therethrough;

5 a hollow insert secured to said hub in fluid communication with the chamber therein, said insert extending outwardly from said hub;

a first section of flexible tubing having distal and proximal ends;

10 means for connecting the proximal end of said first section of tubing in fluid communication with said insert; and

a second section of flexible tubing having distal and proximal ends, said second section of tubing being radiopaque;

15 the proximal end of said second section of tubing extending in sealing engagement over the distal end of said first section of tubing such that said sections of tubing are in fluid communication.



9. The catheter of Claim 8, wherein said first section of tubing comprises a length of tubing of predetermined size constructed of material selected from the group consisting of plastic and elastomeric materials

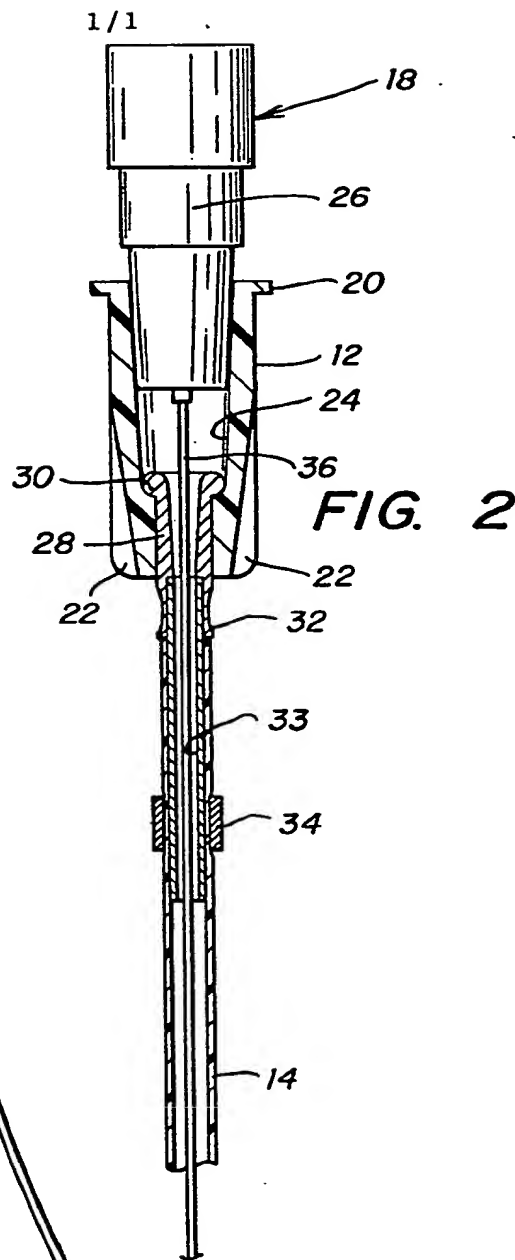
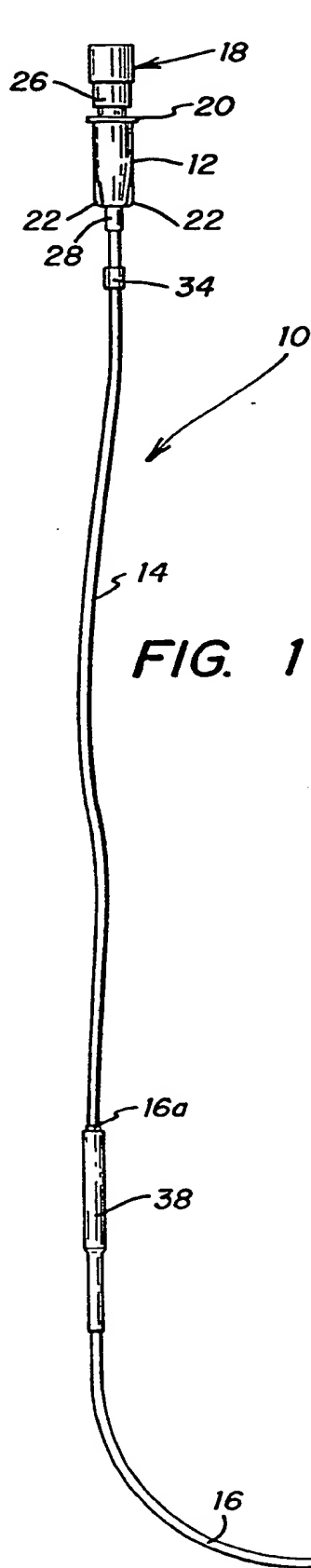
10. The catheter of Claim 8, wherein said second section of tubing comprises a length of tubing of predetermined size constructed from silicon elastomer.

11. The catheter of Claim 8, wherein the chamber in said hub is longitudinally tapered and substantially circular in cross section.

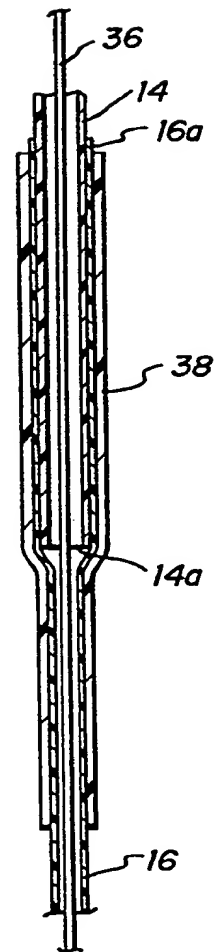
12. The catheter of Claim 8, including:  
flexible sleeve means surrounding the connection between said first and second sections of tubing.

13. The catheter of Claim 8 including:  
removable stylet means extending through said hub, first section of tubing, and a portion of said second section of tubing for reinforcing said catheter during  
5 insertion.





**FIG. 3**



# INTERNATIONAL SEARCH REPORT

International Application No PCT/US80/01540

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (If several classification symbols apply, indicate all) *		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int. Cl.	A61M/25/00	
U.S. Cl.	128/349	
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched *		
Classification System	Classification Symbols	
U.S.	128/349, 348, 350, 656-658, Dig. 16 214, 214.4, 221	
Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched *		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT</b> <sup>14</sup>		
Category *	Citation of Document, <sup>15</sup> with indication, where appropriate, of the relevant passages <sup>17</sup>	Relevant to Claim No. <sup>18</sup>
X	N, Pediatrics, issued December 1975, Vol. 56, No. 6, BORDS et al Reduced Thrombus Formation With Silicone Elastome (Silastic) Umbilical Artery Catheters. Pg. 2, paragraph bridging columns 1 and 2 and last page, column 1, lines 34-39	1-13
X	US, A, 3,958,557, Published 25 May 1976, SHARP et al	4,5-8,12
X	US, A, 3,921,631, Published 25 November 1975 THOMPSON	7,13
A	US, A, 4,068,659, Published 17 January 1978 MOOREHEAD	7,13
A	US, A, 3,720,210, Published 13 March 1973 DIETRICH	1,4,5,8,11
A	US, A, 3,633,585, Published 11 Jan. 1972 McDONALD, JR.	1-3,8-10
A	US, A, 3,605,750, Published 20 September 1971 SHERIDAN et al	1,8
<p>* Special categories of cited documents: <sup>16</sup></p> <p>"A" document defining the general state of the art</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document cited for special reason other than those referred to in the other categories</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but on or after the priority date claimed</p> <p>"T" later document published on or after the international filing date or priority date and not in conflict with the application, but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance</p>		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search <sup>1</sup>		Date of Mailing of this International Search Report <sup>2</sup>
03 March 1981		10 MAR 1981
International Searching Authority <sup>3</sup>		Signature of Authorized Officer <sup>4</sup>
ISA/U.S.		Stephen C. Pellegrino